The Final Frontier in THA: **Bearing Surfaces**

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This Morning's Agenda

- Brief History of THA Bearing Surfaces
- Literature Review & Clinical Experience
- Today's Technologies
  - *Polyethylene*
  - *Highly Crosslinked Polyethylene*
  - *Metal-on-Metal*
  - *Ceramic-on-Ceramic*
  - *Tomorrow's Technologies...*
- ***Which Bearings Are Right For Your Patients?***

History of THA Bearing Surfaces

- Ivory
  - 1922
- Metal-Metal (Stainless Steel)
  - 1938
- Plexiglas
  - 1946
- Teflon
  - 1955
- High-Density Poly
  - 1959
- UHMWPE
  - 1962
- Ceramics
  - 1970

Brief History of Bearing Surfaces


Sir John Charnley

- **Dr. Charnley & UHMWPE**
  - First used: 1962
  - Often referred to as "High Density" until mid-1960s.
  - One of first materials to be subjected to rigorous simulator study
  - "Proved" that Metal-on-Metal designed failed due to frictional torque

Brief History of Bearing Surfaces

- **1980s**
  - Hylamer
  - Heat-Pressed Poly
  - Poly II
  - ArCom® Direct Compression Molded Poly
- **1990s**
  - Highly Crosslinked Poly
  - ArCom® Isostatically Molded Poly
- **2000s**
  - 2nd Generation Highly Crosslinked Poly

ArCom XL

Brief History of Bearing Surfaces

Early Metal-on-Metals

- 1959: Sivash
  - 28 mm
- 1964: Ring
  - 40mm
- 1965: Müller
  - 37 and 42mm
- 1965: McKee-Farrar
  - 38 and 41mm

Derek Edgar

Exhibit 36

VF 12-12-18

PLAINTIFF'S EXHIBIT 269
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Brief History of Bearing Surfaces

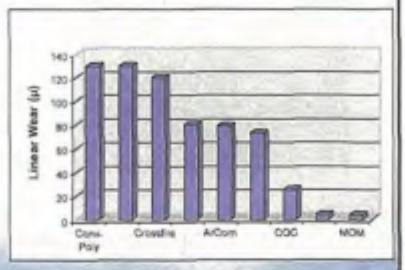
Early Ceramics

- First tried in 1970s
- More extensive use in 1980s with 1st generation materials
- Many failures related to ceramic and poor cup designs
- Current generation FDA approved in February 2003

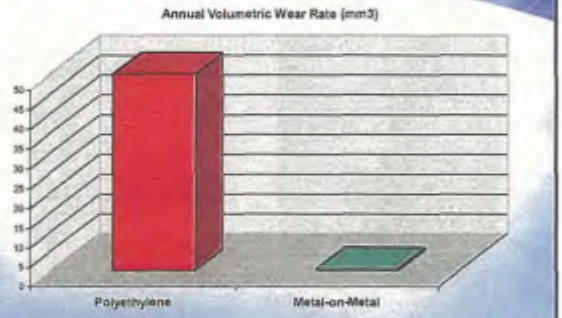
Maher et al. JOR, June, 2004

Bearing Surface Literature Review

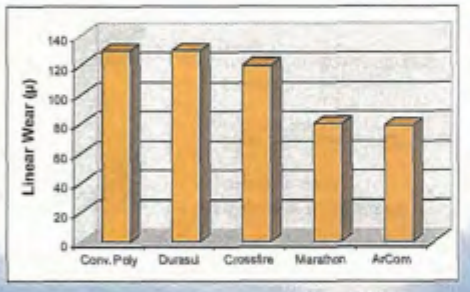
- Conventional Poly (Head)
  - 130 μ/yr
- Durasul (Digas)
  - 130 μ/yr
- Crossfire (Martell)
  - 120 μ/yr
- ArCom (Head)
  - 79 μ/yr
- HXLP (Oonishi)
  - 73 μ/yr
- COC (Hamadouche)
  - 25 μ/yr
- COC (Walter)
  - 4 μ/yr
- MOM (Schmidt)
  - 4 μ/yr



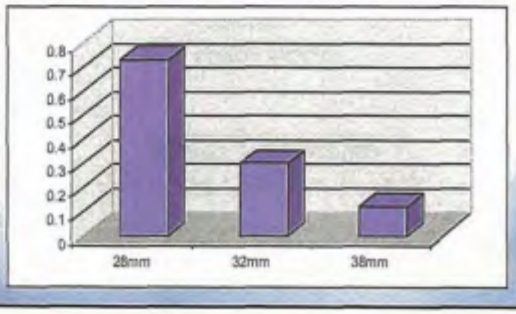
Poly v. Metal Literature Review



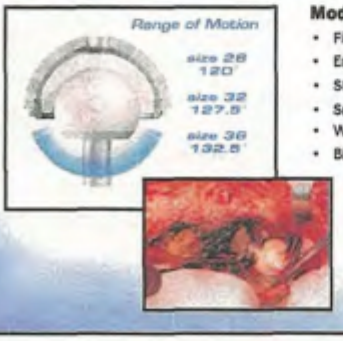
Poly Wear Literature Review



Metal Wear Testing Review



Modern Ceramics



Modern Ceramics

- First released in 2003
- Encore Medical
- Stryker Orthopedics
- Smith-Nephew
- Wright Medical
- Biomet (predicted 2H 2005)

The Future of Bearings

Diamond-on-Diamond

- Hardest possible bearing surface
- Potential for multiple variations (taper or 1pc)
- No fracture risk
- No measurable wear
- In development currently; expected to become commercially available within a few years

Your Options Today

Polyethylene

- Predictable wear pattern
- Best option since the 1960s
- Versatile (10-degree, hi-wall, etc.)
- Proven to fail consistently

Ceramic-on-Ceramic

- Ultra-low wear rate
- Improved materials
- Fracture is always catastrophic
- Mediocre ROM
- Must pull stem if articulation fails

Metal-on-Metal

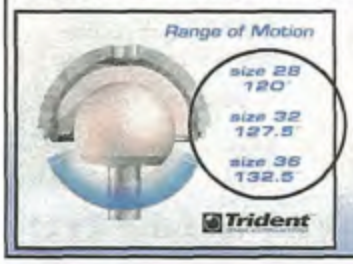
- Ultra-low wear rate
- Extremely high ROM (160 deg)
- Multiple design options
- Proven (in use since 1950s)
- Ion release?
- Hypersensitivity?

Oxinium™

- No risk of fracture
- Ceramic wear properties
- Been shown to delaminate
- Still forced to use poly

#7 Current Ceramic Designs Limit ROM!

"With the common [ceramic] head diameters, patients with a wide range of motion are a problem because of higher sensitivity to impingement."
(Elke, *Bioceramics in Joint Arthroplasty*, Ceramtec, 2002)

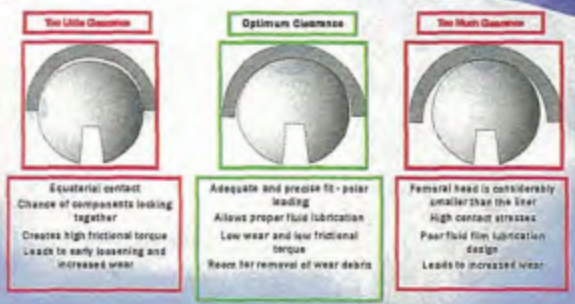


M^2a-Magnum™ = 160 degrees ROM

#2 *In Vivo* 45-year M-M Lessons

- The 1960's taught us that M-M bearings must meet three conditions to function optimally
  - Optimum clearance and polar loading
  - Optimum material and manufacturing processes
  - Optimum design tolerance

#2 *In Vivo* 45-year M-M Lessons

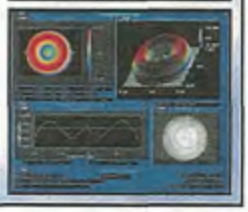


#2 Dimensional Control (Fluid Film)

- "Suction Effect"
- Exclusive to MOM
- Made possible by precise tolerances

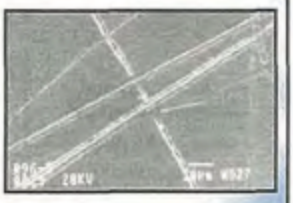
#2 Dimensional Control

- 100% of devices
- Radius
  - CMM
- Sphericity
  - Zygo system
- Surface Finish
  - Zygo system
  - Visual inspection



#3 Self-Polishing!

- Metal-metal phenomena
- Repairs surface damage
- Retrieval analysis
  - Scratches smoothed
  - Gliding movements
- Prevents catastrophic wear



McKellop et al. *5th World Bio Congress*, 1996

#3 Ceramics Can't Self-Polish

- Stripe wear occurred in 11/15 revisions.
- All "3rd generation" Alumina or Zirconia heads.
- Occurs in deep flexion activities
- Seen in 50% of COC revisions.

Walter et al., JOA, June, 2004

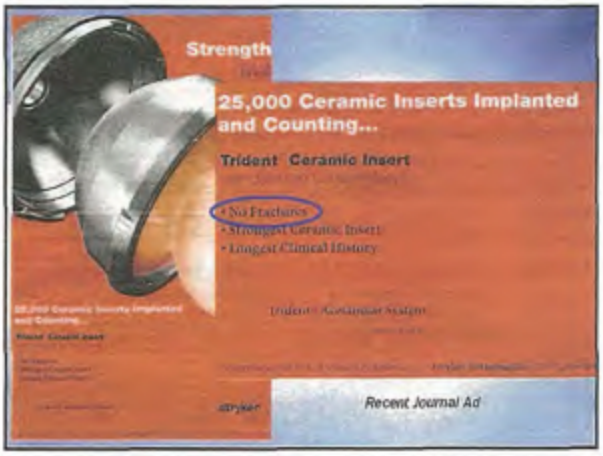
#3 HXLPE Does Not Self-Polish

- 21 melted HXLP liners retrieved after an average of 10 months *in situ*
- 79% showed evidence of pitting
- 96% showed evidence of scratching
- 67% showed evidence of surface cracking
- "Findings may be associated with decreased ductility and fatigue resistance."

#4 No Risk of Fracture!

- Before 1990 13.4% ceramic fracture rate (Willmann)
- Numerous published reports of ceramic fractures:

Allain	McLean
Pulham	Suzuki
Mattenlis	Mangione
Wanda	Jager
Fritsch	Calloway
Toni	Kempf
Higuchi	Wisser
Otsuka	Nizard
Piero	Heisel
Kuo	Sedel



Recent Journal Ad

#4 Trident® COC Can Fracture

- 1 Alumina HD Revised for FX 2000
- 4 Alumina HDs Revised for FX 2002
- 1 Alumina HD Revised for FX 2003
- 1 Alumina HD Revised for Scratches 2003
- 2 Trident® Liners Revised for FX 2003

FDA's MAUDE Database as of Oct. 2004
http://www.fda.gov/cdrh/

#4 Ceramics and HXLP Risk Fracture

- Ceramic manufacturers claim 1/25,000
  - 9 chipped liners with the ABC cup.
  - 5 chipped liners, 1 FX in the Wright Medical study.
  - 1 FX and 2 liner chips in the Encore Study.
  - 11 FX in the Implex Study (since suspended).
- Over 317 ceramic head fractures from St. Gobain (recalled)
- 47 of 3,000 alumina COC fractured (Kyocera, Japan -recalled)

Metal-on-Metal Does Not Fracture.

Fulam, et al. JBJS 1997

#4 Zirconia Ceramic Failures

"...the combination of the tunnel-sintering and subsequent machining operations had probably interacted to make the TH-balls extremely vulnerable to transformation to the monoclinic phase in vivo. *This had not been detected by the company's standard quality control checks and proof tests.*"

Clarke, JBJS, 2003

#4 Weakened HXLP Risks Fracture

"Laboratory tests have demonstrated that the cross-linking of polyethylene improves wear performance but may also reduce the material's strength. The case of our patient demonstrates a limitation in the use of these systems."

- **Mechanically Weakened Poly**
- **40mm Head = 3mm poly**
- **Vertical Cup**
- **10 months in vivo and Rim FX**

Halley and Greenwald et al, JBJS April 2004

Metal-on-Metal Does Not Fracture.

#5 Osteolysis with M-M is Extremely Rare!

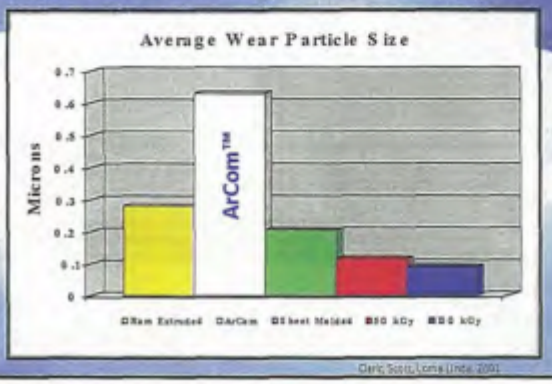
- Ceramic particles have been reported to cause lysis and therefore are not bioinert as claimed.
- Yoon - 103 COC hips - 7.6 years avg. F/U
- 22% femoral lysis
- 49% acetabular lysis

Immediate Post-Op

9 Years Later

Yoon et al., JBJS, 1998

#5 HXLP Not Yet Clinically Proven to Solve Lysis

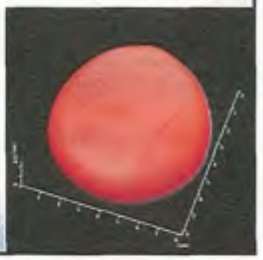


Clark, Scott, Loma Linda 2001

#5 HXLP Not Yet Clinically Proven to Solve Lysis

1. 130,000 conventional polyethylene particles will fit in one red blood cell.
2. 1.4 million HXLPE particles will fit in one red blood cell.
3. Reducing wear volume does not necessarily mean a reduction in particulate burden on the surrounding tissues.

Clarke, Alt. Bearings Symp. 2004

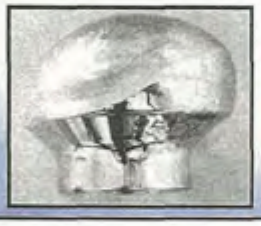


#6 M-M is Easy to Revise!

- "The most important disadvantage to ceramics is the fact that component failure leads to almost **unsolvable problems with the remaining particles.**"
  (Elke, *Bioceramics in Joint Arthroplasty*, Ceramtec, 2002)
- 24 months after revision for **fractured ceramic head**...sharp-edged ceramic particles...too small to be seen by the surgeons unaided eye.. embedded in the polyethylene.
  (Kempf, et al., AOTS, 1990)

#6 Ceramic Particles Can Create a Revision Nightmare!

"Particles of alumina were found in thirteen hips (39%), either in the surrounding tissues (seven hips) or embedded in the polyethylene cup (six)."
Allain et al., JBJS, 2003



#6 No particulate or design issues affecting revision!

Recommended removing cup and stem (perform synovectomy?) if revision is required.

- Pulliam, et al., JBJS, 1997
- Allain, et al., JBJS, 2003
- Krikler, JBJS, 1998
- Ceramtec Literature

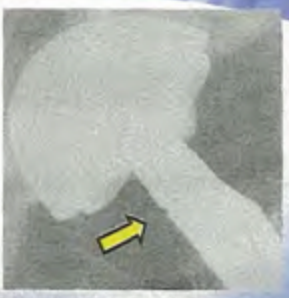
#7 Increased ROM and Stability

M²a-Magnum™ 160° + ROM!

#7 Stability (Jump Distance/Hop Height)

- 2.2cm average
- Must travel greater distance to "jump" out of the cup
- Approx. ½ the head size

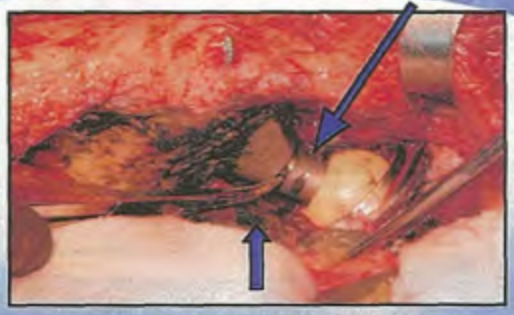
COC Revision at 3 Yrs



Notching on stem

COC Revision at 3 Yrs

Notched Stem



Visible black staining (Ti6-4)

Worn Metal Rim on Liner

Titanium-Titanium Wear

#8 Lots of Design Options!

- COC Has Just 3 Neck Lengths
  - "Because such a small range [of neck lengths] is available, it is advisable to use a conservative neck cut and remove more neck as necessary to properly restore neck length."
    Garino, *CORR*, 2000
  - M^2a = 7 neck lengths

#8 Lots of Design Options!

#8 M-M = Big Heads in Small Cups!

#9 Lengthy and Positive Clinical History!

- 20 years of not-so-positive clinical data on the first two generations of COC vs. 40+ years of good clinical data with first and 2nd generation MOM
- 3rd generation ceramics have limited clinical data
  - Clinical reports of chipping, difficulty during insertion
  - Anecdotal reports of chipping, breakage, difficulty during insertion
  - Recent suspension of Implex study due to liner pull out and breakages
  - Worldwide recall of "3rd generation" ceramics due to nearly 400 head fractures
- Will we see a 4th generation ceramic?
- Current HXLPE has <5 yrs clinical history.

#10 What About Ion Release?

SPINECORE Inc.

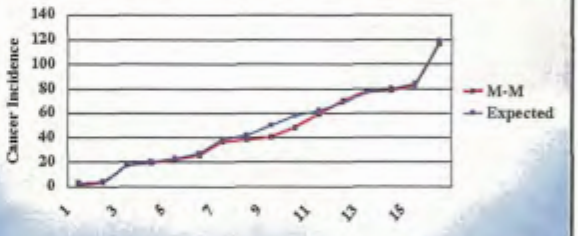
Zimmer's Website Now Reads:

"There is no identified increased risk of cancer with a metal-on-metal articulation that was used in the past, nor has there been any identified with Metasul..."

"[Ion Release is] a theoretical concern that is most commonly used as a commercial argument against Metasul by companies that do not have the product."

#10 What About Ion Release?

Positive Clinical History Despite Ion Release Concerns!



Visuri CORR 1996

#10 Metal Ion Studies Inconclusive

- Tharani et al. -
  - 9 studies evaluated
  - ranging from 6 months to 17 years
  - Conclusion: "the available data do not support a causal link between THA and the development of cancer."
- Merritt et al-
  - "...It is clear at this stage in total joint replacement, that more reported adverse biologic responses are occurring (due) to the polyethylene than to the metal"

#10 Metal Ion Studies Inconclusive

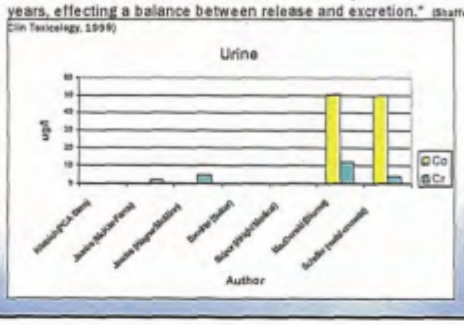
Brodner, et al.

- "Toxic serum levels of cobalt after release from implants have not been observed , nor is there any evidence of cobalt-associated pathology..."
- "Cobalt and chromium concentrations of the 3 umbilical cord sera were below the detection limit. This indicates that at the time of delivery the placenta acts as an effective barrier for cobalt and chromium disseminated from M-M articulations."

Journal of Bone and Joint Surgery 1997
M-M International Symposium, Montreal 2003

Ions Release = Excretion

- "We conclude that the elimination of Co and Cr proceeds over several years, effecting a balance between release and excretion." (Shaffer et al., Clin Toxicology, 1999)



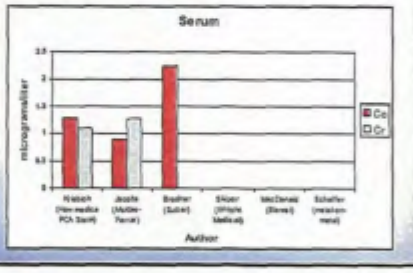
Remember! *Parts-Per-**Billion***

- One billion tennis balls would wrap around the earth's equator 1 ¼ times!
- Average metal ion concentrations found in the serum from MOM THA is 1.5 to 3 ppb/L.
- "Particulate cobalt-chromium alloy was well tolerated by both cell lines (SaOS-2 and MG-63) producing no cytotoxicity at the highest concentration tested (1 million ppb/L)"

Allen, et al., JB/S(Br) May 1997

Metal Ions are Unavoidable in Orthopedics!

- Nails, screws, stems, metal cups, plates, modular CoCr heads, cages, and cables all release ions.
- Loose CoCr stems (Kraay, JBJS Br, 1994)
- COC neck impingement and metal taper junctions release ions.

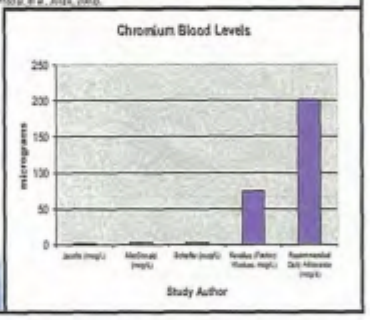


How Much is Too Much?

"Concentrations of chromium in the blood of factory workers are reported to be 20 to 75µg/L in whole blood." (Keraluu, Chromium Symposium, 1986 / Proctor, et al., JOEH, 2002)

"Metal-on-metal ion levels of chromium can also be compared to the studies on worker cohorts who have historically been exposed well above the current permissible standards (IARC, 1990), and have not shown a consistent pattern of elevated cancer incidence." (Proctor, et al., JOEH, 2002)

"USRDA for Chromium 50-200 mcg/d" (Schroeder, Clin Tox, 1968)



In Summary: Why Metal-Metal?

- Great for younger, more active patients
- Low wear -won't ever wear out
- Doesn't fracture, and self-polishes
- Plenty of ROM and design options
- Established clinical history – the original alternate bearing
- One-piece cups conducive to MIH techniques